UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,769	08/17/2006	Ladislav Cvak	TEVGAL 3.3-020	2277
	7590 09/25/200 /ID, LITTENBERG,	08	EXAMINER	
KRUMHOLZ &	& MENTLIK		MABRY, JOHN	
600 SOUTH A' WESTFIELD, I	= :=		ART UNIT	PAPER NUMBER
,			1625	
			MAIL DATE	DELIVERY MODE
			09/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Applica	ation No.	Applicant(s)		
Office Action Summary		10/589	,769	CVAK ET AL.		
		Examin	ier	Art Unit		
		John Ma	abry, PhD	1625		
Period fo	- The MAILING DATE of this commun r Reply	ication appears on t	he cover sheet v	with the correspondence a	ddress	
A SHO WHIC - Exten after 9 - If NO - Failur Any re	DRTENED STATUTORY PERIOD FOR HEVER IS LONGER, FROM THE MISSIONS of time may be available under the provisions SIX (6) MONTHS from the mailing date of this commo period for reply is specified above, the maximum state to reply within the set or extended period for reply sply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b).	AILING DATE OF of 37 CFR 1.136(a). In no nunication. atutory period will apply and will, by statute, cause the a	THIS COMMUN event, however, may a d will expire SIX (6) MC application to become A	ICATION.  a reply be timely filed  DNTHS from the mailing date of this ABANDONED (35 U.S.C. § 133).		
Status						
2a)⊠ 3)□	Responsive to communication(s) file This action is <b>FINAL</b> .  Since this application is in condition closed in accordance with the practic	2b)∏ This action is for allowance exce	pt for formal ma	•	ne merits is	
Dispositi	on of Claims					
5)⊠ 6)□ 7)□ 8)□	Claim(s) <u>2-23</u> is/are pending in the ala) Of the above claim(s) is/a Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restrict	re withdrawn from o				
Application	on Papers					
10) -	The specification is objected to by the The drawing(s) filed on is/are: Applicant may not request that any object Replacement drawing sheet(s) including The oath or declaration is objected to	a) accepted or ction to the drawing(s the correction is requ	s) be held in abeya uired if the drawin	ance. See 37 CFR 1.85(a). g(s) is objected to. See 37 (	, ,	
Priority u	nder 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) Notice 3) Inform	(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (Pation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date	'TO-948)	Paper No	Summary (PTO-413) o(s)/Mail Date Informal Patent Application 		

## Response to Amendment(s)

Applicant's response on May 5, 2008 filed in response to the Office Action dated November 2, 2007 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

# 35 USC § 112 Rejection(s)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The 112-2<sup>nd</sup> rejection of claims 1-23 regarding the term "extracting" have been overcome in view of Applicants amendment to the claim.

### 35 USC § 103(a) Rejection(s)

Applicant's arguments with respect to 103(a) rejections have been fully considered and are persuasive. The 103(a) rejection of claims 1-23 regarding obviousness over Lek (GB 1,299,557) in view of Keating (Lecture Notes) have been withdrawn.

The rejection of claims 1-23 under 35 U.S.C. 103(a) as unpatentable over Cvak (1999) has been fully considered and is partially persuasive.

Applicant argues that Cvak refers to the use of various organic solvents for the extraction of ergot, namingly "methylenechloride, trichloroethylene, ethyl acetate, acetone, methylisobutyl ketone and mixtures of toluene with methanol or ethanol and

ether with ethanol..." and that the reference does not teach or suggest the concentrations of ethanol and/or toluene in such a mixture claimed.

The Examiner maintains the rejection of claims 2-23 under 35 U.S.C. 103(a) as unpatentable over Cvak (1999).

Cvak (1999) teaches that mixtures of toluene with ethanol are used to extract ergot. Cvak does not teach or suggest specific concentrations of ethanol and/or toluene mixtures. However, one of ordinary skill in the art would be motivated to experimentally try varying concentrations of toluene-ethanol in order to optimize the percentage of ergot alkaloid extracted.

Cvak (1999) also suggests that the use percolation technology is used to reach satisfactory yields, using a battery or percolators or some type of a continual extractor (see second full paragraph under *Ergot Extraction*, page 375). Additionally, it is common for an artisan of ordinary skill to perform extractions at ambient temperature.

Further, Examiner clearly argues in Non-Final Action (bottom of page 6 and 7) that a crystallization process would be obvious in view Lek (GB 1,299,557). The case was made that Lek discloses a process for isolating ergot alkaloids, which comprises of extracting ergot with toluene, an organic, water immiscible solvent. The ergot extract was then filtered through alumina then dissolved in ethanol then the toluene-ethanol extract was partially evaporated and ergot alkaloid then crystallized from solution. Excess petroleum ether (hexanes) was then added to aid in the crystallization and then collected (see page 1, lines 40-75).

Additionally, Cvak (1999) discloses that two main separation techniques are used for purification of ergot extracts, one of which is crystallization using both bases and their salts. The term salts implies that a acid-base extraction purification process was employed (see *Purification of Ergot Alkaloids*, page 376).

Claims 2-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cvak (1999) in references mentioned above. The adjustment of particular conventional working conditions (e.g. determining result effective amounts of the ingredients beneficially taught by the cited references), as well as adjustment of reaction temperature, reaction time and use of solvents, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan (*In re* Mostovych, Weber, Mitchell and Aulbach, 144 USPQ 38). Accordingly, these types of modifications would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

### Status of the Claims

Claims 2-23 are pending and rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/589,769 Page 6

Art Unit: 1625

/John Mabry/ Examiner Art Unit 1625

> /Rita J. Desai/ Primary Examiner, Art Unit 1625